DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

April 14, 2004

**WARNING LETTER**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

**Refer to MIN 04 – 23**

John M. Vosters
President
Tidy View Dairy, Inc.
N3603 Vanden Bosch Road
Kaukauna, Wisconsin 54130

Dear Mr. Vosters:

A tissue report received by the U.S. Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residues in cows that originated from your dairy farm. On February 3-25, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection at your dairy farm located in Kaukauna, WI. That inspection confirmed that you offered two dairy cows for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug which is unsafe within the meaning of Section 512. A food is adulterated under Section 402(a)(4) of the Act if the food has been held under insanitary conditions whereby it may have been rendered injurious to health.

You also caused the adulteration of animal drugs because the drugs were used in a manner that does not conform to their approved uses or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (copy enclosed). This caused the animal drugs to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about September 2, 2003, you sold a dairy cow identified with back tag number 35GM1823 (your cow #3507) for slaughter as human food. USDA analysis of tissue samples collected from this cow identified the presence of flunixin at

0.128 parts per million (ppm) in the liver. On or about September 14, 2003, you sold a dairy cow identified with back tag number 35HW7858 (your cow #1430) for slaughter as human food. USDA analysis of tissue samples collected from that cow identified the presence of flunixin at 0.7080 parts per million (ppm) in the liver. Flunixin is not approved for use in lactating or dry dairy cows (per 21 CFR 522.970(e)(2)(iii), copy enclosed). The presence of flunixin in the edible tissue of these dairy cows causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example, you failed to maintain complete and accurate treatment records and failed to assure that medicated animals were withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs in edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

As stated above, flunixin is not approved for use in lactating or dry dairy cows. However, the extralabel use of an approved veterinary or human drug is permitted if it complies with Sections 512(a)(4) and (a)(5) of the Act, and 21 CFR Part 530. Our investigation found that your extralabel use of flunixin failed to comply with these requirements. 21 CFR 530.11(a) prohibits extralabel use by a lay person except when under the supervision of a licensed veterinarian. Your dairy farm used flunixin without adequate supervision of a licensed veterinarian. 21 CFR 530.11(d) prohibits any extralabel use that results in a residue exceeding an established safe level, safe concentration or tolerance. Your use of flunixin resulted in an illegal drug residue. Because your extralabel use of flunixin was not in compliance with 21 CFR Part 530, the drug is unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

Our investigation also found that your dairy farm is using sulfadimethoxine 12.5% oral solution in an extralabel manner by administering the drug intravenously to lactating dairy cattle. Approved uses of sulfadimethoxine oral solution are listed in 21 CFR 520.2220a, copy enclosed. The extralabel use of sulfonamide drugs (such as sulfadimethoxine) in lactating dairy cattle is prohibited by 21 CFR 530.41(a)(9). Your extralabel use of sulfadimethoxine 12.5% oral solution causes the drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violations of the Act. Similarly, it is not necessary for

you to personally ship an adulterated drug in interstate commerce. The fact that you caused the adulteration of animal drugs that had been shipped in interstate commerce is sufficient to hold you responsible.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also, include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosures: 21 CFR 530, 522.970, 520.2220a